

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989]

**§ 872.3850 Gutta percha.**

(a) *Identification*. Gutta percha is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth. The gutta percha is softened by heat and inserted into the root canal, where it hardens as it cools.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989]

**§ 872.3890 Endodontic stabilizing splint.**

(a) *Identification*. An endodontic stabilizing splint is a device made of a material, such as titanium, intended to be inserted through the root canal into the upper or lower jaw bone to stabilize a tooth.

(b) *Classification*. Class II.

**§ 872.3900 Posterior artificial tooth with a metal insert.**

(a) *Identification*. A posterior artificial tooth with a metal insert is a porcelain device with an insert made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to replace a natural tooth. The device is attached to surrounding teeth by a bridge and is intended to provide both an improvement in appearance and functional occlusion (bite).

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994]

**§ 872.3910 Backing and facing for an artificial tooth.**

(a) *Identification*. A backing and facing for an artificial tooth is a device intended for use in fabrication of a fixed or removable dental appliance,

such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994]

**§ 872.3920 Porcelain tooth.**

(a) *Identification*. A porcelain tooth is a prefabricated device made of porcelain powder for clinical use (§ 872.6660) intended for use in construction of fixed or removable prostheses, such as crowns and partial dentures.

(b) *Classification*. Class II.

**§ 872.3930 Tricalcium phosphate granules for dental bone repair.**

(a) *Identification*. Tricalcium phosphate granules for dental bone repair is a device intended to be implanted into the upper or lower jaw to provide support for prosthetic devices.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 872.3.

**§ 872.3940 Total temporomandibular joint prosthesis.**

(a) *Identification*. A total temporomandibular joint prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. The effective date of the requirement for premarket approval has not been established. See § 872.3.

[59 FR 65478, Dec. 20, 1994]

**§ 872.3950 Glenoid fossa prosthesis.**

(a) *Identification*. A glenoid fossa prosthesis is a device that is intended to be implanted in the temporomandibular joint to augment a

glenoid fossa or to provide an articulation surface for the head of a mandibular condyle.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* The effective date of the requirement for premarket approval has not been established. See § 872.3.

[59 FR 65478, Dec. 20, 1994]

**§ 872.3960 Mandibular condyle prosthesis.**

(a) *Identification.* A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* The effective date of the requirement for premarket approval has not been established. See § 872.3.

[59 FR 65478, Dec. 20, 1994]

**§ 872.3970 Interarticular disc prosthesis (interpositional implant).**

(a) *Identification.* An interarticular disc prosthesis (interpositional implant) is a device that is intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* The effective date of the requirement for premarket approval has not been established. See § 872.3.

[59 FR 65478, Dec. 20, 1994]

## Subpart E—Surgical Devices

**§ 872.4120 Bone cutting instrument and accessories.**

(a) *Identification.* A bone cutting instrument and accessories is a metal device intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw. The device includes the manual bone drill and wire driver, powered bone drill, rotary bone cutting handpiece, and AC-powered bone saw.

(b) *Classification.* Class II.

**§ 872.4130 Intraoral dental drill.**

(a) *Identification.* An intraoral dental drill is a rotary device intended to be attached to a dental handpiece to drill holes in teeth to secure cast or preformed pins to retain operative dental appliances.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994]

**§ 872.4200 Dental handpiece and accessories.**

(a) *Identification.* A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

(b) *Classification.* Class I.

[55 FR 48439, Nov. 20, 1990]

**§ 872.4465 Gas-powered jet injector.**

(a) *Identification.* A gas-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a cartridge containing pressurized carbon dioxide which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification.* Class II.

**§ 872.4475 Spring-powered jet injector.**

(a) *Identification.* A spring-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification.* Class II.

**§ 872.4535 Dental diamond instrument.**

(a) *Identification.* A dental diamond instrument is an abrasive device intended to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument